

REGULATORY SUPPORT SYSTEM FLOWSHEET

WHO

All sites participating in adult NCI-sponsored Cooperative Group clinical trials (Phase I-III) except exempt prevention trials*

The Cancer Trials Support Unit (CTSU) in collaboration with Westat, Oracle Inc., The Coalition of National Cancer Cooperative Groups, and representatives from each adult Cooperative Group has developed the CTSU Central Regulatory Office. The CTSU Central Regulatory Office is the central document intake and storage facility located at the Coalition of National Cancer Cooperative Groups, Inc., in Philadelphia, PA.

WHY

The Regulatory Support System (RSS) database and the CTSU Central Regulatory Office have been designed to track regulatory compliance in an effort to reduce the administrative and regulatory burden on the Cooperative Groups, permitting the Groups to focus on the science of conducting clinical trials.

WHAT

- The Regulatory Support System (RSS) located at the CTSU Central Regulatory Office contains regulatory documents for **ALL** adult NCI-sponsored Cooperative Group clinical trials (*except exempt prevention trials**)
- Documents to be submitted for **ALL** Cooperative Group regulatory documents include:
 - **Initial IRB approvals**
 - **IRB-approved consent forms** (*when mandated*)
 - **Continuing review approvals**
 - **Amendment / Revision approvals** (*when mandated*)
 - **Protocol-specific regulatory requirements**

WHEN

All regulatory documents must be submitted to the CTSU Central Regulatory Office as soon as possible following IRB approval.

WHERE

CTSU Central Regulatory Office
1818 Market Street
Suite 1100
Philadelphia, PA 19103
Fax: 215-569-0206

REQUIRED DOCUMENTS

The following **must** be included in each regulatory documentation submission to the CTSU:

1. CTSU IRB Transmittal Sheet
2. CTSU IRB Certification Form
 - **Protocol Number and Version Date** (*when mandated*)
 - **Protocol Title** (*partial or short version acceptable*)
 - **Institution Name and NCI Institution Code**
 - **Name of Principal Investigator and NCI Investigator Number**
 - **Required by the IRB: Review, Approval Type, Date of Approval, IRB Number, Expiration Date and Signature of IRB Official and Contact Information for Questions 9 through 20**

Helpful Tools can be found on the CTSU RSS web page (www.ctsuo.org)

- eCourse
- CTSU online Operations Manual
- RSS Frequently Asked Questions
- Memo for Institutions Participating in the CIRB Program
- CTSU IRB Certification Form
- CTSU IRB Transmittal Sheet
- Guidance Document for Regulatory Forms

For more information, visit www.ctsuo.org or call 1-888-823-5923

Exempt Prevention Trials Include :

STAR, SELECT, BCPT, PCPT, P-3, GOG-0190, MC9944, SWOG S9808 and SWOG S0316*